

## RISK MANAGEMENT

Karen Hulebak, Chief Scientist  
Office of Public Health and Science, Food Safety and Inspection Service  
U.S. Department of Agriculture

Good afternoon. It's a pleasure to be here with you today to talk about the role of risk management in reducing foodborne illness and improving food safety.

The process of risk analysis, which consists of risk assessment, risk management, and risk communication, is playing an increasingly important role in establishing public policy for food safety within governments, both domestically and internationally. Risk management is the process of food safety regulators weighing alternatives in light of the results of risk assessment, the regulatory authority provided by domestic law(s), and other information, and selecting and implementing the appropriate control option(s), including new regulatory measures where appropriate.

The benefits of this approach to establishing public food safety policy are many. First, it strengthens the role of science in informing risk management decisions. Second, it allows risk managers to shift from what I characterize as the traditional shotgun approach to policy and regulation, to a more focused approach targeted at the most effective control measures. For example, if a risk assessment pinpoints particular products that may be more likely to cause foodborne illness, we can focus our strategy accordingly.

While the role of science has been recognized as important in managing food safety risks, we need to further strengthen the role it plays domestically and worldwide. For example, in 1997, all Federal agencies with food safety risk assessment responsibilities established the Interagency Risk Assessment Consortium. The Consortium is charged with advancing the science and effectiveness of microbial risk assessment by (1) encouraging joint research to develop predictive models and other tools that can be used to conduct risk assessments, and (2) filling data gaps in this area. A clearinghouse was also established to collect and catalogue resources on risk analysis.

Let me review for you the eight principles of food safety risk management, developed in 1997, by the Food and Agriculture Organization of the United Nations, in collaboration with the World Health Organization.

- 1) First, risk management should follow a structured approach, which includes risk evaluation, assessing risk management options, implementing management decisions, and monitoring to see if adjustments are needed.
- 2) Second, human health protection should be the primary consideration in risk management decisions. Decisions on acceptable risk levels should not be based upon arbitrary or unjustified differences in risk exposure.
- 3) Third, the rationale for risk management decisions should be transparent. All elements of the process, including decision-making, should be systematically identified and documented to ensure all interested stakeholders understand the decision rationale.

- 4) Fourth, risk managers should provide a risk assessment policy framework for risk assessors. Risk assessment policy, which sets the guidelines for value judgements and policy choices, may need to be applied at specific decision points during the risk assessment process. Such policy is preferably established in advance of risk assessment and in collaboration with risk assessors.
- 5) Fifth, risk assessment and risk management should remain functionally separate to ensure the scientific integrity of the risk assessment process. While interaction between risk managers and risk assessors is essential, these processes should remain separate to reduce any conflict of interest.
- 6) The sixth principle of food safety risk management is that decisions should take into account the numerical uncertainty expressed in the risk assessment. While risk assessments are scientifically-based, the full meaning of the results should be framed by the degree of uncertainty. Risk managers need to consider and understand the reasons and range of uncertainty.
- 7) The seventh principle is that risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.
- 8) The last principle of food safety risk management is that it should be a continuous process, taking into account newly generated data and periodically reviewing risk management decisions. Technology and research continuously reveal new information, and we must understand that a decision based on the science of today, may need to be changed tomorrow as new information is revealed.

### **HACCP as a Risk Management Strategy**

The Hazard Analysis and Critical Control Point (HACCP) system approach implemented by meat and poultry establishments in the U.S. is a good example of a risk management strategy. It also helps to illustrate the importance of the eighth principle of food safety risk management – that is risk management should be a continuous process. HACCP is a science-based process control system used by meat and poultry establishments to prevent, eliminate, or reduce to acceptable levels, the significant food safety hazards that may arise in particular processes and products.

HACCP systems are designed to evolve with science, and as science reveals new information regarding food safety hazards, industry HACCP plans must be reviewed and revised accordingly. Additionally, our regulations require meat and poultry establishments to reassess their HACCP plans at least annually, and whenever any changes occur that could affect the hazard analysis that forms the basis for the HACCP plans in particular establishments.

For example, if new data revealed that a pathogen was more prevalent than previously thought, establishments would be required to reassess their hazard analyses to determine if that pathogen is a hazard reasonably likely to occur in their operation. If it is reasonably likely to occur, then it must be addressed in the HACCP plan.

## **Risk-Based Inspection**

Now that HACCP has been implemented nationwide in meat and poultry establishments, we are interested in taking the next step of applying a risk-based approach to the allocation of inspection resources within meat and poultry processing establishments, to the extent possible under the law. For example, under the current approach all processing establishments are assumed to have an equal need for inspection. FSIS is exploring, with the Research Triangle Institute and Texas A&M University, the development of a new approach that will facilitate a more risk-based allocation of inspection personnel to processing establishments, potentially resulting in more inspection in some and less in others.

Under such a risk-based approach, the need for inspection could be based on a systematic evaluation of the relative risks presented by each establishment based on such factors as: 1) the type of raw materials and product produced, 2) the processes used to produce it, 3) the volume of product, and 4) the compliance history of the establishment.

By more effectively factoring hazard and risk considerations into the current inspection approach, the Agency can more effectively execute its inspection responsibilities, further assure the safety of meat and poultry products, and efficiently use its limited inspection resources. FSIS plans to have a public meeting on this approach later this year, and will evaluate input received at the meeting to decide how best to proceed.

## **Farm-to-Table Approach**

While FSIS efforts have historically focused on the inspection of meat and poultry slaughter and processing establishments, the Agency's public health mandate requires that pre- and post- processing hazards also be considered as part of a comprehensive strategy to further reduce foodborne risks. To complement HACCP and the risk management strategies taken within those establishments, we are working with all interested parties to develop and encourage farm-to-table steps to improve food safety. It is important to emphasize that mandatory regulations are not the only risk management tools available to managers. Research, education, and voluntary efforts on the part of industry are important as well.

The Agency's recently completed risk assessment for *Salmonella enteritidis* in eggs is an example of a coordinated, farm-to-table approach. For the risk assessment, effects of pathogen growth were modeled at various points throughout the farm-to-table chain and results revealed specific points where intervention strategies should be focused. Depending on the point along the farm-to-table continuum where an intervention strategy was suggested, the best entity to initiate and implement a strategy may be a federal agency, state and local agency, and/or industry itself. Obviously, industry would be an integral part of any strategy.

The Egg Safety Action Plan announced in December 1999, which was developed in response to the Risk Assessment on *Salmonella enteritidis* in eggs, further illustrates the benefits of a farm-to-table strategy and coordination among various stakeholders. The action plan was developed jointly by six federal agencies – FSIS, Animal and Plant Health Inspection Service, Agriculture Marketing Service, Agriculture Research Service, the Food and Drug Administration, and the Centers for Disease Control and Prevention. The plan identified intervention strategies from production to consumption to reduce, and ultimately eliminate eggs as a source of SE illnesses.

We all have a responsibility for improving food safety, and we all need to work together to reduce human foodborne illness. In doing so, we can work toward a goal of creating a seamless food safety system, with improved coordination among all segments of the farm-to-table chain.

### **International Implications**

In working towards this goal, we must also coordinate with our international food safety partners. Risk assessments play an important role in international trade by ensuring that countries establish food safety requirements that are scientifically sound and by providing a means for determining equivalent levels of public health protection between countries. Without a systematic assessment of risk, countries may set import requirements that are not related to food safety, and could create artificial barriers to trade.

Recognizing the importance of this science-based approach to food safety and fair trade, the World Trade Organization requires each country's food safety measures to be based on risk assessment. And the Codex Alimentarius Commission has drafted principles for risk analysis. In April 2001, the Codex Committee on General Principles will meet in Paris, France to discuss them. These principles being developed by Codex will encourage all countries to incorporate risk analysis into their future food safety decisions.

### **Closing**

In closing, we're off to a good start in integrating risk analysis into our food safety policy making process here in the U.S., but we still have work ahead of us to more fully integrate this concept. Investments involved in furthering the science of risk analysis and applying it effectively to foods will be well worth the returns in terms of providing a safer food supply for the American public, and consumers around the world.